

Testimony of Peter Lurie, MD, MPH

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U.S. Environmental Protection Agency Public Hearing on the Proposed Rule Titled  
“Strengthening Transparency in Regulatory Science”

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My name is Dr. Peter Lurie and I am the president of CSPI, the Center for Science in the Public Interest. CSPI is an independent science-based health advocacy organization with over 500,000 members. We accept no industry or government donations and carry no advertising in our *Nutrition Action Healthletter*. Prior to joining CSPI, I served at the Food and Drug Administration as Associate Commissioner for Public Health Strategy and Analysis, where for several years I led the agency’s Transparency Initiative. Over the course of my career, I have authored numerous academic articles on transparency.<sup>1</sup>

CSPI is a firm advocate of scientific transparency. Our Integrity in Science Project investigated, exposed, and sought to reduce corporate influence on science and science-based public policy for many years. More recently, CSPI led a call for the National Library of Medicine to be more transparent in publishing conflict of interest disclosures. But EPA’s proposed rule is *not* about transparency or strengthening science. Instead, it is a wolf of pro-industry bias hiding in the sheep’s clothing of transparency in science. The proposal should be withdrawn.

Transparency is not about restricting the use of sound science as this proposal would do; it is about communicating openly and clearly about the action taken, the strengths and limitations of the science used, and making that science and interpretation as available to the public as possible. Certainly,

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<sup>1</sup> A partial list of my published articles relating to transparency is appended to this testimony.

the more transparent a government agency can be about the nature and limitations of the data underlying a decision, the better. But the failure to meet some abruptly and arbitrarily elevated standard for disclosure cannot and should not be grounds for the summary exclusion of data that were rigorously gathered and reported.

The surest tests of any scientific transparency policy are: 1) whether it was itself developed transparently, and 2) whether it promotes transparent, rigorous, science-based decision-making in an even-handed manner. The proposal fails on both counts.

First, this proposal violates fundamental tenets of transparent rulemaking. EPA apparently failed to consult with relevant stakeholders such as scientific, research, or health professional associations, did not consult with other federal agencies, and did not even make the proposed rule available to its own Scientific Advisory Board for review.<sup>2</sup> In addition, the proposal lacks critical citations and documentation or even an adequate justification for why it was proposed. Rather than furnishing the evidentiary support required for administrative action, the agency has merely adopted a legislative initiative<sup>3</sup> that failed to pass despite support from the energy, chemical, manufacturing, and other key industries. That legislation was proposed by Rep. Lamar Smith (R-TX), Chair of the House of Representatives Committee

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<sup>2</sup> EPA Science Advisory Board. Memorandum: Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14). May 12, 2018, [https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/\\$File/WkGrp\\_memo\\_2080-AA14\\_final\\_05132018.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf).

<sup>3</sup> H.R.1430 - HONEST Act. <https://www.congress.gov/bills/115th-congress/house-bill/1430>.

on Science, Space, and Technology, who questions the science behind climate change<sup>4</sup> and the relationship between air pollution and mortality.<sup>5</sup>

Moreover, despite its professed fealty to cost effectiveness in rulemaking, the proposed rule provides no cost-effectiveness analysis whatsoever. It simply asserts blithely that “EPA believes the benefits of this proposed rule justify the costs.” But the rule would be costly indeed: analyses of an earlier version of Rep. Smith’s legislation from the nonpartisan Congressional Budget Office predicted costs of \$250 million per year over the next few years.<sup>6</sup>

But even more important, the proposal will not meet its purported scientific goals and will instead undermine the scientific basis for decision-making by the agency. Since its inception, EPA has developed rules with demonstrable efficacy in protecting the public by relying in large part upon the kinds of data that EPA would now preclude from consideration. Some of EPA’s greatest public health accomplishments, such as eliminating lead in gasoline and classifying secondhand smoke as a cause of cancer (which led to banning smoking from indoor public places), were based on the kinds of data that would be discarded under the proposal. Such data are widely used in rulemaking proceedings by other U.S. government agencies and around the world. It is particularly troubling that the proposal also opens the door to a reconsideration of past rules, which would be utterly inappropriate under prevailing principles of administrative law.

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<sup>4</sup> For example, see Tollefson J. Controversial chairman of US House science committee to retire. *Nature*, November 2, 2017. <https://www.nature.com/news/controversial-chairman-of-us-house-science-committee-to-retire-1.22954>; and Lavelle M, Hasemyer D. Instrument of power: How fossil fuel donors shaped the anti-climate agenda of a powerful congressional committee. *Inside Climate News*, December 5, 2017. <https://insideclimatenews.org/news/05122017/lamar-smith-congress-climate-change-fossil-fuel-industry-house-science-committee>.

<sup>5</sup> Servick K. House panel subpoenas EPA for all pollution data. *Science*, August 2, 2013. <http://www.sciencemag.org/news/2013/08/house-panel-subpoenas-epa-air-pollution-data>.

<sup>6</sup> Congressional Budget Office. Cost Estimate, H.R. 1030 Secret Science Reform Act of 2015, As ordered reported by the House Committee on Science, Space, and Technology on March 3, 2015, March 11, 2015. <https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/costestimate/hr1030.pdf>.

In fact, the proposal would have an effect opposite to its claimed purpose; it would suppress important and relevant science conducted in large part by the best minds in academia and government, thereby unduly restricting the evidence available to EPA and potentially favoring data developed by industry. Most academic epidemiologic studies rely on aggregated data and other means to protect the privacy of their human subjects. In other cases, researchers conducting the studies may be prevented from making the underlying data publicly available for legal, practical, or ethical reasons.

The pro-industry orientation of the proposal is revealed once more in its assault on the linearity assumption in the dose/concentration-response function. (This approach assumes that there is no safe threshold at the population level for most chemical pollutants.) This assault runs counter to the advice provided to EPA by the National Research Council, which stated, "The committee recommends that cancer and noncancer responses be assumed to be linear as a default."<sup>7</sup> In another departure from its claimed commitment to transparency, EPA provides no scientific citations for its claim of "growing empirical evidence of non-linearity in the concentration-response function for specific pollutants and health effects." But what is most telling about the discussion of linearity is its inclusion in the proposed rule in the first place; there is simply no need to raise it in a proposed rule supposedly about transparency.

A legitimate approach to strengthening transparency in regulatory science would heed the advice provided by the National Academies to use the best and most current science to support and revise default assumptions, make implicit defaults explicit, and provide clear standards for the level of

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<sup>7</sup> National Research Council. Science and Decisions: Advancing Risk Assessment. Washington, D.C.: National Academies Press; 2009, p. 180.

evidence needed to depart from default assumptions,<sup>8</sup> taking into account data-sharing guidelines already developed by NIH.<sup>9</sup>

Let me close with the question with which EPA should have started: What is the problem that this proposed rule seeks to fix? Where is the study for which the lack of access to raw data resulted in misinterpretation or in the promulgation of an inappropriate regulatory standard? To the contrary, the record is replete with studies that formed the basis of health- and life-saving regulations that would now be precluded from use and that might even provide a basis for the revocation of rules enacted in the distant past.

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<sup>8</sup> Institute of Medicine of the National Academies. Identifying and Reducing Environmental Health Risks of Chemicals in Our Society: Workshop Summary. Washington, D.C.: National Academies Press; 2014, p. 55.

<sup>9</sup> NIH. Data Sharing Policy and Implementation Guidance. March 5, 2003.  
[https://grants.nih.gov/grants/policy/data\\_sharing/data\\_sharing\\_guidance.htm#app](https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#app).

### Examples of articles by Peter Lurie relating to transparency

Lurie P. Suggestions for improving conflict of interest processes in US Food and Drug Administration Advisory Committees—past imperfect. JAMA Internal Medicine 2018. doi:10.1001/jamainternmed.2018.1324.

Cruz ML, Xu J, Kashoki M, Lurie P. Publication and reporting of the results of post-market studies required by the US Food and Drug Administration in 2009-2013. JAMA Internal Medicine 2017;177:1207-10.

Xu J, Emenanjo O, Ortwerth M, Lurie P. Association of appearance of conflicts of interest with voting behavior at FDA Advisory Committee meetings—a cross-sectional study. JAMA Internal Medicine 2017;177:1038-40.

Lurie P, Chahal HS, Sigelman DW, Stacy S, Sclar J, Ddamulira B. Comparison of content of FDA letters not approving applications for new drugs and associated public announcements from sponsors: cross sectional study. BMJ 2015;350:h2758. doi:10.1136/bmj.h2758.

Ross JS, Nazem AG, Lurie P, Lackner JE, Krumholz HM. Updated estimates of pharmaceutical company payments to physicians in Vermont. Journal of the American Medical Association 2008;300:1998-2000.

Ross JS, Lackner JE, Lurie P, Gross CP, Krumholtz HM. Pharmaceutical company payments to physicians: early experiences with disclosure laws in Vermont and Minnesota. Journal of the American Medical Association 2007;297:1216-23.

Lurie P, Zieve A. Sometimes the silence can be like the thunder: access to pharmaceutical data at the FDA. Law and Contemporary Problems 2006;69:85-97.

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Michaels D, Montforton C, Lurie P. Selected science: an industry campaign to undermine an OSHA hexavalent chromium standard. Environmental Health 2006;5:5.